

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., a Delaware corporation,)	
and THE CURATORS OF THE)	
UNIVERSITY OF MISSOURI, a public)	
corporation and body politic of the State of)	
Missouri,)	
)	C.A. No. 07-551 (GMS)
Plaintiffs,)	(CONSOLIDATED)
)	
v.)	
)	
PAR PHARMACEUTICAL, INC., a Delaware)	
corporation,)	
)	
Defendant.)	

PLAINTIFF SANTARUS, INC.'S
REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS

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A. The Court Does Not Have Jurisdiction Over Par's Counterclaim Related To The '737 Patent

The fact that the '737 patent is in reissue proceedings distinguishes this case from *Teva Pharms. U.S.A., Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007). Like *Teva*, Par's arguments for jurisdiction are based on the premise that a declaratory judgment can bring future patent certainty. Unlike in *Teva*, however, this Court cannot provide such certainty because the '737 patent is in reissue proceedings. See, e.g., *Vardon Golf Co. v. Karsten Mfg. Corp.*, 294 F.3d 1330, 1334 (Fed. Cir. 2002) (trial court decision "rendered moot" when original patent surrendered during reissue). The *Teva* court found significant the fact that Novartis was holding patents "in reserve," rather than permitting them to be challenged. *Teva*, 482 F.3d at 1344. Quite the opposite is true here. The University of Missouri affirmatively has submitted the '737 patent to scrutiny before the PTO.

Moreover, Par disregards the fact that declaratory judgment jurisdiction requires not just a dispute causing injury to Par (standing), but also that the issue presented be ripe for judicial determination. *Id.* at 1337 ("Thus, *MedImmune* teaches that in a declaratory judgment action, 'all the circumstances' must demonstrate that a justiciable Article III 'controversy' exists. A justiciable Article III controversy requires the party instituting the action to have standing *and the issue presented to the court to be ripe.*") (emphasis added). As Judge Farnan noted in *Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 525 F. Supp. 2d 680, 686 (D. Del. 2007), "the question of whether a new patent will ever be reissued is speculative, purely hypothetical," making a declaratory judgment claim unripe. This conclusion is consistent with decades of Supreme Court precedent on ripeness that emphasize both the Constitutional and practical groundings of the doctrine.

See, e.g., Nat'l Park Hospitality Ass'n v. Dept. of the Interior, 538 U.S. 803, 808 (2003) ("The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise.") (internal quotations omitted); *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967) ("[Ripeness] is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.").

Par's reliance on 35 U.S.C. § 252 demonstrates why its '737 patent counterclaim is not ripe for adjudication. Par intimates that the potential for substantially identical claims **in the reissue patent** creates present hardship involving the **'737 patent as it now exists**. Par Brief at 8-9. It is, of course, pure speculation on Par's part that section 252 would even apply here. At present, there are no reissued claims against which to assess the applicability of section 252. The section 252 issue may never ripen into an actual controversy between the parties, and the harm Par asserts never be realized. This type of speculative harm stemming from problems that may never require resolution does not make the '737 patent ripe for adjudication. *Texas v. United States*, 523 U.S. 296, 302 (1998).

Finally, Par attempts to sidestep the fact that the University of Missouri has placed the '737 patent into reissue by arguing that it **might**, at some time in the future, seek to terminate the reissue proceedings and assert the '737 patent against Par. Par's argument simply underscores the hypothetical nature of the present "dispute." As the Supreme Court has explained: "A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Id.* at 300 (internal quotations omitted). Whether the '737 patent will reissue or the

proceedings terminated sooner, whether the claims will be amended, what those hypothetical amendments will be, and whether any such claims will read on Par's ANDA product, are all, at this point, matters of speculation that cannot support the exercise of jurisdiction.

B. The Court Should Decline Jurisdiction Over Par's Counterclaim Related To The '737 Patent

Even if jurisdiction over Par's counterclaim relating to the '737 patent were constitutionally permissible, this Court should exercise its discretion to decline to hear that counterclaim. Par does not, and cannot, contest that this Court lacks jurisdiction over the nascent reissue patent that might result from the reissue application. As a result, this Court cannot adjudicate matters such as infringement and validity of claims not yet even allowed by the PTO. Moreover, any decisions regarding the claims of the current version of the '737 patent are unlikely to control as to amended or new claims in a reissue patent. *Vardon Golf*, 294 F.3d at 1333. Given that this Court does not have the power to declare the unreissued patent invalid or non-infringed, Par's insistence that the parties waste resources taking discovery, drafting expert reports, and potentially engaging in claim construction hearings concerning patent claims that will soon disappear is puzzling. In the worst case scenario, this Court would make a full determination of validity and infringement, and then have that determination mooted by the reissue of the '737 patent. *Id.* at 1334 (trial court decision "rendered moot" when original patent surrendered during reissue).

It appears that Par is seeking to litigate the pending '737 reissue patent before it even is granted. For example, Par urges the Court to make a preliminary and advisory claim construction of the word "powder," and to decide that it does not create a

difference in the scope of claim 1 in the reissue patent. Par Brief at 15-16. Setting aside the obvious principle that the scope of a claim can turn on a single word, the Court does not have jurisdiction over the hypothetical reissue patent that has yet to be granted. Par's effort to litigate the potential reissue patent in this case simply creates a series of traps for the parties to fall into as each toes the ground between permissible issues of litigation and asking the Court for an advisory opinion.

Par also argues that its allegation of the disfavored defense of infectious inequitable conduct is so compelling that it requires the Court to assert jurisdiction over the '737 patent. *See Eaton Corp. v. Parker-Hannifin Corp.*, C.A. No. 00-751, 2003 WL 179992, at *1 (D. Del. Jan. 24, 2003) ("Inequitable conduct charges are disfavored by this court and charges of 'infectious inequitable conduct' even more so."). This motion is neither the time nor the place to argue the lack of merit of Par's claims. What is clear, however, is that Par did not believe the '737 patent needed to be part of the suit when it asserted the same inequitable conduct defense in C.A. No. 07-551-GMS.¹

Moreover, Par's reliance on its right to certainty in launching its product as justification for jurisdiction is misplaced. For the reasons addressed in the previous section, this Court cannot provide certainty with respect to a reissue patent that has yet to be granted. Attempting to litigate these issues today will achieve only confusion, not certainty.

¹ In C.A. No. 07-551-GMS, Par asserted an inequitable conduct defense and counterclaims with respect to the three patents asserted by Plaintiffs, but asserted no counterclaim on the '737 patent. That case was subsequently consolidated with C.A. No. 07-827-GMS, in which Par filed the '737 patent declaratory judgment counterclaim that is the subject of this motion.

C. This Court Should Stay Par's Counterclaim Related To The '737 Patent

Par offers no persuasive argument why, if the Court were to decide to exercise jurisdiction over the '737 patent, a stay should be denied pending the results of the reissue proceeding. Instead of addressing the undeniable waste associated with litigating the infringement and validity of a patent that will ultimately be surrendered, Par offers only farfetched or inapposite arguments. Par argues that a stay would put it at a tactical disadvantage because the Plaintiffs, having successfully argued that the current version of the '737 patent should not be litigated in this case, will immediately turn around, halt the reissue proceedings, and assert that patent against Par. Par Brief at 9. Par does not explain why it believes such an unlikely series of events will occur, or what the Plaintiffs might gain from such an unusual litigation strategy (other than the ire of the Court).

Par also argues that a stay would allow the Plaintiffs to sue Par for infringement of the reissue patent, once it issues. Par does not contest that this Court lacks jurisdiction over the pending reissue patent, and it is not clear how a stay of litigation related to the current '737 patent has any relationship to the prospect of litigation involving the reissued patent. *Pfizer*, 525 F. Supp. 2d at 687. Finally, Par's argument that the "Plaintiffs sacrifice nothing" is misplaced. The issue is whether a stay prejudices the non-moving party. There is no requirement that the moving party must be harmed. *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, C.A. No. 06-514, 2007 WL 2892707, at *4 (D. Del. Sept. 30, 2007). In any event, in this case, both parties, as well as the Court, would benefit by avoiding devoting time and resources to disputes over patent claims that may be mooted by the grant of a reissue patent.

Par fails to present a clear argument rebutting the Plaintiffs' position that a stay would help clarify the issues in the case. Par offers no reason this Court should indulge in the exercise of shooting at moving targets of validity and infringement rather than waiting until the reissue proceeding is concluded. Instead, Par merely reiterates its argument for infectious unenforceability. As discussed above, however, the '737 patent need not be part of this litigation for Par to make that argument.

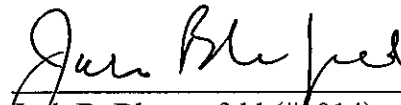
Finally, Par argues that the Plaintiffs were so dilatory in their request for a reissue that Par necessarily is prejudiced. The cases cited by Par have no similarity to this one. In the first, the Court denied a stay requested by the plaintiff **seven months after the close of discovery**. *Freeman v. Minnesota Mining & Mfg. Co.*, 661 F. Supp. 886, 888 (D. Del. 1987). In the second, the Court denied a stay when the motion was made **less than three weeks before the close of discovery**. *Cognex Corp. v. Nat'l Instruments Corp.*, C.A. No. 00-442, 2001 WL 34368283 (D. Del. June 29, 2001). Here, the '737 patent was placed into reissue before the litigation commenced and the motion for a stay was made before the start of any discovery. Par's assertions notwithstanding, the fact that the Plaintiffs might have requested a reissue earlier is not relevant. The early stage of this case, the potential wasteful expenditure of judicial resources, the likely clarification of the key issues of infringement and invalidity, and the possible needless complication of multiple litigation all favor a stay of Par's counterclaim insofar as it relates to the '737 patent.

D. Conclusion

Par's declaratory judgment counterclaim is based on speculative future harm and requires this Court to evaluate the hypothetical claims of a non-existent reissue

patent. Indeed, Par's arguments in favor of jurisdiction all rest upon the sort of "contingent future events that may not occur as anticipated, or indeed may not occur at all," that the Supreme Court has held make a claim not ripe for adjudication. *Texas*, 523 U.S. at 300. Even if the Court finds that it has jurisdiction, this is a case in which the exercise of such jurisdiction will serve no useful purpose. The Court should decline Par's invitation to expend time and resources litigating issues of infringement and validity that likely will be mooted by the PTO reissue proceedings. Par's declaratory judgment counterclaims should be dismissed, or in the alternative stayed pending termination of the reissue proceedings.

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March 17, 2008

CERTIFICATE OF SERVICE

I hereby certify that on March 17, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

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